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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,215	08/01/2000	John F. O'Connor	54205-A-PCT-US/JPW/SHS/MV	7218

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/630,215	O'CONNOR ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response filed 11/28/03 is acknowledged and has been entered.

Claims 58-67 are pending and remain under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. In light of Applicant's amendment, the rejection of claims 58-67 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

3. In light of Applicant's arguments, the rejections of claims 58-67 under 35 U.S.C. 112, first paragraph, is hereby, withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 58-67 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53, 59, 60, 65, 71, 72, and 77-82 of copending Application No. 09/017, 976, now US Patent 6,500,627, for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The instant claims are drawn to a method for predicting pregnancy outcome in a subject using a monoclonal or polyclonal antibody to bind to an early pregnancy-associated molecular isoform of hCG (EPMI-hCG). The monoclonal or polyclonal antibody is described in the specification as being generated by a well-characterized antigen, C5-hCG, and as being able to bind to an epitope present in EPMI-hCG. EPMI-hCG, is likewise, said to be recognized by a monoclonal antibody, B-152 which is deposited with the American Type Culture Collection under Designation No. HB-12467. However, since the recitation "which isoform is recognized by the B152 antibody deposited with the American Type Culture Collection under Designation No. HB-12467" does not partake in the actual method steps of the claim, such recitation bears no patentable weight. Additionally, it is proper for purposes of obviousness rejection to interpret "early pregnancy associated molecular isoform of hCG" as any "early

pregnancy factor or EPF", absent a definitive and distinctive characterization of this hCG isoform, because unpatented claims are given the broadest interpretation consistent with the specification.

5. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Penfold et al. (US 6,133,048) in view of Morton et al. (WO/ 88/04779, Abstract).

Penfold et al. disclose an assay method for testing pregnancy status by contacting a urine sample from the subject with a capture antibody which specifically binds human chorionic gonadotropin (hCG) and a detection antibody which specifically binds hCG; thus, in the presence of hCG, a complex is formed in a sandwich format. The capture antibody is an anti-hCG monoclonal antibody immobilized on a latex particle. The detection antibody is an anti-hCG antibody in the device's test line to provide a coloured signal indicative of the presence of hCG (see column 3, lines 22-56 and column 1, line 65 to column 2, line 45). Penfold et al. teach application of the assay with other urinary analytes for determination of pregnancy or relevant fertility status by measuring other analytes including luteneizing hormone, cancer markers, etc.

Penfold et al. differ from the instant invention in failing to disclose using anti-EPF antibodies in a sandwich format to allow detection of early pregnancy in the subject.

Morton et al. disclose using anti-EPF antibodies for detecting the presence of EPF in a sample during pregnancy (see Abstract). Morton et al. disclose that EPF is a protein which is detected from serum or urine throughout the first and second trimesters of pregnancy and its continuing production is dependent upon the presence and viability

of an embryo; thus, a marker for determining outcome of pregnancy. Morton et al. specifically generated monoclonal and polyclonal antibodies for use in the method.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the monoclonal antibodies in the sandwich assay taught by Penfold with the anti-EPF monoclonal antibodies as generated by Morton to determine an amount of EPMI-hCG present in a sample because anti-EPF monoclonal antibodies in a sandwich assay would provide clarity and specificity in detection, not only of pregnancy status itself, but also detection of pregnancy outcome has become possible.

6. Claims 58-61, 63, and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penfold et al. (US 6,133,048) in view of Morton et al. (WO/ 88/04779, Abstract), and in further view of Birken et al. (Endocrinology, 1993).

Penfold et al. and Morton et al. have been discussed supra. Penfold et al. and Morton et al. differ from the instant invention in failing to disclose contacting the EPMI-hCG with a second capture antibody and a second detection antibody in a sandwich assay.

Birken et al. teach a two-site immunoradiometric assay used to evaluate immunopotency of nicked HcG. Birken et al. teach using a capture antibody that specifically binds INN HcG (intact HcG heterodimer) and a detecting (tracer) antibody that likewise, specifically binds INN HcG. The capture antibody is B109 and the I^{125} radiolabeling antibody is B108. (See page 1391, column 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to further incorporate monoclonal antibodies in the sandwich assay method taught by Penfold and modified by Morton with the method taught by Birken because Birken specifically taught that use of two-site immunometric assay provides advantage in monitoring complex hCG functions.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
February 19, 2004

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641